IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO: MDL No. 2327
CASES IDENTIFIED IN **EXHIBIT 1**

PLAINTIFFS' MEMORDANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF JERRY BLAIVAS, M.D.

Plaintiffs respectfully submit this Memorandum of Law in Opposition to Defendants Ethicon, Inc. and Johnson & Johnson's ("Defendants") Motion to Exclude Certain Opinions of Jerry Blaivas, M.D. and Memorandum in support thereof ("Def. Brief").

I. INTRODUCTION

As this Court has previously noted, "Dr. Blaivas is a urologist and one of the pioneers of sling surgery for women with sphincter incontinence. He has extensive experience treating patients with complications related to synthetic sling surgery." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 718 (S.D.W.Va. 2014). Dr. Blaivas is a board-certified clinical and academic urologist with over thirty (30) years of clinical experience: (1) he is highly educated and intensively trained in his field of expertise; (2) has extensive experience with pelvic mesh and its complications; (3) has authored numerous texts on urogynecological surgery and related subjects; (4) relies upon hundreds of peer-reviewed articles in reaching his conclusions; (5) was one of the pioneers of sling surgery for women with sphincter incontinence; and, (6) acted as Editor-in-Chief of the Neurourology and Urodynamics Journal for twenty-six years. *See*

generally, Def. Ex. B (TVT Expert Report and Blaivas CV)[1]. Based on his familiarity with relevant published medical and scientific literature, and his own clinical experiences (reviewing patient records and rendering diagnoses and/or treating patients with surgical mesh injuries and chronic pelvic pain), Dr. Blaivas is qualified to testify about the use of synthetic mesh during urogynecological surgeries and his testimony will be helpful to the jury.

Dr. Blaivas is proffered to testify about the safety and efficacy of the autologous sling procedure as used to treat women with stress incontinence. Dr. Blaivas is also being offered to testify about the nature and occurrence of complications caused by synthetic midurethral slings, including the TVT, TVT-O, TVT Secur, and TVT Exact devices ("the TVT Devices"), as well as Prolift, which is used to treat Pelvic Organ Prolapse. *See*, Def. Exs. B-G, (Blaivas Expert Reports). Dr. Blaivas pioneered the autologous sling procedure and for years has been a "surgeon of last resort" for women who experience complications resulting from stress incontinence surgery. Because of his unparalleled experience as a surgeon, Journal editor, and pioneer in the field of urogynecology, Dr. Blaivas is in a unique position to compare the safety and efficacy of vaginal procedures utilizing synthetic mesh and alternative procedures such as the autologous sling procedure.

II. Legal Standard

For the sake of brevity and because this Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard for the admissibility of expert testimony. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104. The trial judge acts as a

[1] For convenience to the Court, Plaintiffs will cite to Exhibits attached to the Defendants' Motion to Exclude as "Def. Ex.__."

gatekeeper for scientific, technical and other specialized knowledge. *See, Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 288 (1993); *see also, Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 141 (1999).

III. Argument

A. Dr. Blaivas Employs the Same Standard of Academic Rigor in the Courtroom that he Employs in his Medical Practice

This Court found Dr. Blaivas qualified to offer testimony, and that the basis for Dr. Blaivas' opinions was both reliable and sound, in both this MDL and MDL No. 2326, *In re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation*. *See, Huskey v. Ethicon, Inc.*, 29 F.Supp 3d 691, 718 (S.D.W.Va. 2014); *see also, Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 521 (S.D.W.Va. 2014), as amended (Oct. 29, 2014). In *Huskey v. Ethicon, Inc.*, this Court stated "Dr. Blaivas is a urologist and one of the pioneers of sling surgery for women with sphincter incontinence. . . . He has extensive experience treating patients with complications related to synthetic sling surgery." 29 F. Supp. 3d at 718. This Court determined that Dr. Blaivas was qualified to testify about the adequacy of warnings in the IFU, under-reporting of mesh complications, and the knowledge of physicians in general as it related to the standard of care for designing a mesh product and warning about potential risks. *Id.* This decision is of specific note here as Dr. Blaivas has offered substantially the same report and the same opinions in these Wave cases as he did in *Huskey*; indeed, the testimony was so similar that no additional deposition was taken of Dr. Blaivas on the TVT-O report because Ethicon could point to no new additions or changes that would require an new deposition.

Despite the fact that Dr. Blaivas has been qualified by this Court before to offer the same opinions on one of the slings in this TVT family of products, Ethicon points instead to a decision by this court in *Frankum v. Boston Scientific Corp*. as their basis for excluding Dr. Blaivas'

testimony in these Ethicon cases involving different products and different reports. 2015 U.S. Dist. LEXIS 57251 at *15 (S.D. W. Va. May 1, 2015). This argument is misplaced for two separate reasons: (1) the deposition transcript and reports in *these* cases establish conclusively that Dr. Blaivas has used appropriate and complete methodology in reaching his opinions concerning the Ethicon products; and (2) Dr. Blaivas has subsequently offered deposition testimony in the Boston Scientific cases to establish that the methodology that was used to reach the conclusions in the Boston Scientific cases was also sound.

First, this Court has routinely cautioned parties that it will not simply adopt prior *Daubert* rulings, particularly in the face of a new deposition transcript or new report. As this Court recently held:

> I am compelled to comment on the parties' misuse of my previous Daubert rulings on several of the experts offered in this case. The parties have, for the most part, structured their Daubert arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert's* core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Winebarger v. Boston Sci. Corp., 2015 U.S. Dist. LEXIS 53892, 10-11 (S.D. W. Va. Apr. 24, 2015). Here, this requires the parties to examine the complete record before them, and not to piecemeal an attempt to shoehorn all expert opinions into a prior ruling.

Turning to this set of facts, the record here establishes that Dr. Blaivas has used appropriate methodology to reach his opinions *in this case*. Additionally, since his December 2014 deposition, Dr. Blaivas was the lead author for a review article published in the prestigious

Nature Reviews Urology entitled, "Safety considerations for synthetic sling surgery.[2]" The article synthesizes and contextualizes a comprehensive review of all peer-reviewed literature involving the complications associated with polypropylene mid-urethral slings. The paper is supported by 397 references. The Safety Considerations Review contains the following conclusions which are consistent, *if not identical*, with the opinions expressed in Dr. Blaivas' initial Rule 26 report[3]:

1. The long-term effectiveness of RP or TOT slings, as measured by subjective and/or objective instruments suggests that rates of cure or improvement of SUI after implantation are high and compare favorably to the autologous pubovaginal sling. Ex. 2 at p.4.

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[2] *See*, Blaivas, J. G. et al., Safety Considerations for Synthetic Sling Surgery. Nat. Rev. Urol. 2015 Sep;12(9):481-509. (Epub2015 Aug 18) attached hereto as **Exhibit 2** (hereinafter "Safety Considerations").

[3] The conclusions reached in Dr. Blaivas's Rule 26 Reports and in his Safety Considerations article are further supported by other recent publications: (1) Ford AA and Ogah JA. *Retropubic or transobturator mid-urethral slings for intrinsic sphincter deficiency-related stress urinary incontinence in women: a systematic review and meta-analysis.* Int Urogynecol J. 2015 Jul 29. [Epub ahead of print]; (2) Constantini E, et al. *Long-term efficacy of the trans-obturator and retropubic mid- urethral slings for stress urinary incontinence: update from a randomized clinical trial. World J Urol.* 2015 Aug 1. [Epub ahead of print]; (3) Tomaselli GA, et al. *Tension-free vaginal tape-obturator and tension-free vaginal tape-Secur for the treatment of stress urinary incontinence: a 5-year follow-up randomized study.* Eur J Obstet Gynecol Reprod Biol. 2015 Feb; 185:151-5.; (4) Brubaker L, et al. *Missing data frequency and correlates in two randomized surgical trials for urinary incontinence in women.* Int Urogynecol J. 2015; 26:1155-1159; (5) Barski D and Deng DY. *Management of mesh complications after SUI and POP repair: Review and analysis of the current literature.* Biomed Res Int. 2015;2015:831285. Doi: 10.1155/2015/831285. [Epub 2015 Apr 20]; (6) Nilsson CG. *Creating a gold standard surgical procedure: the development and implementation of TVT.* Int Urogynecol J. 2015 Apr;26(4):467-9; (7) Ralph G, et al. *The failed idea of a "gold standard."* Int Urogynecol J. 2015; 26:1405-1406; (8) Lee D, et al. *Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes.* Expert Rev Med Devices. 2015 Mar;12(2):201-16; (9) Kirby AC, et al. *Midurethral slings: which should I choose and what is the evidence for use?* Curr Opin Obstet Gynecol. 2015; 27:359-365; (10); Iakovlev VV, et al. *Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted form patients.* 2015:00B:000-000; (11) Bendavid R, et al. *Mesh-related SIN syndrome. A surreptitious irreversible neuralgia and its morphologic background in the etiology of post-herniorrhaphy pain. Int J Clin Med.* 2014; 5:799-810; and (12) Imel A, et al. *In vivo oxidative degradation of polypropylene pelvic mesh.* Biomaterials. 2015 Dec;73:131-41.Attached hereto as, **Exhibits 3-14**.

2. The poor quality of studies makes it challenging to track the incidence, severity, and consequences of various retropubic and/or transobturator sling complications. *Id*.

3. Considerable evidence exists that SMUS complications are underreported. *Id*.

4. Based on the available data, the literature reports that a minimum of 12.5% of women who undergo mesh SMUS surgery have a serious adverse event and/or surgical failure. *Id*. at p.6.

5. Chronic disabling pain is one of the most common indications for mesh removal, particularly in patients fitted with TOT slings (like the Obtryx). In comparison with patients with an RP sling, patients with a TOT sling have a higher incidence of persistent pain (32% versus 10%) and dyspareunia (18% versus 3%). This finding is confirmed by a review and meta-analysis in which the rates of chronic groin and leg pain were higher in patients with a TOT sling compared with those of patients with an RP sling (16% versus 6.5%, respectively). *Id*.at p.14.

6. Inflammatory reactions, fibrosis, deformation, nerve entrapment, degradation, shrinkage/contraction, migration, and stiffening are mechanisms for mesh-related complications and symptoms. *Id*.

The record here establishes that Dr. Blaivas used the appropriate standard to meet the *Daubert* threshold for reliability and admissibility of his opinions. Here, Dr. Blaivas specified in each of his Wave 1 Expert Reports that all of the opinions he seeks to give are "to a reasonable degree of medical certainty" and that he, "applied the same scientific rigor that he uses in all aspects of his professional activities, including caring for patients, publishing, lecturing, consulting with other healthcare professionals, and serving as a litigation expert." *See*, Def. Exs. B-G, (Blaivas Expert Reports), at p. 3.

Furthermore, at his deposition concerning the report utilized here for the TVT device, Dr. Blaivas testified at length about his conclusions in his Safety Considerations article, the methodology used in forming those opinions, and the fact that the methodology that he used in his expert reports is the same as the methodology utilized when preparing his peer reviewed publications. *See*, Def. Ex. H, (Deposition of Jerry Blaivas, M.D., taken on September 24, 2015)

at 398:10-399:20. In his deposition, Dr. Blaivas testified that his opinions in the report were based on:

> First, my own personal experience with mesh, with mesh complications and with my firsthand knowledge of what my peers and the medical community at large that I interact with, what their opinions were and what they knew about the potential of mesh to cause complications . . . The second part is my review of the medical literature and tempered with a third part is my rather unique awareness of the medical literature because I was editor and chief for so many years of the major journal that dealt with these kinds of things.

Id. Dr. Blaivas also testified that he had read and relied on more articles for his expert report than he has for his peer reviewed publications. *Id.* at 415:6-12. There is nothing in any deposition transcript associated with any of the Ethicon cases currently pending before the Court that established that Dr. Blaivas did not use a rigorous methodology when reaching his opinions concerning Ethicon's products that are the subject of this Response. To the contrary, Dr. Blaivas' testimony establishes that he used the same appropriate methodology that he and numerous other experts have used in the past when reaching these opinions.

Furthermore, the cryptic deposition testimony that was the basis for the *Frankum* decision has now been clarified through additional testimony and at least one Court that has considered the matter has allow Dr. Blaivas to testify. Thus, although the record in *Frankum* and other BSC Wave 1 & 2 cases may not have been clear, it is now clear that Dr. Blaivas applies the same intellectual and scientific rigor whether in litigation or in research. *See*, Dep. of Dr. Jerry Blaivas in *Frankum v. Boston Scientific Corp.*, No. 1:15-CV-00091-MOC (W.D.N.C.), taken on May 2, 2016, attached hereto as **Exhibit 15**, at 12:2-13:2 ("I believe that I use the highest possible standard of scientific rigor when I come to the conclusions about legal matters and about medical matters. I use the same criteria for both.") Finally, the trial court hearing the *Frankum* case has allowed Dr. Blaivas to testify concerning his opinions, irrespective of the

deposition testimony, recognizing that those issues are appropriate for cross-examination, and not exclusion under *Daubert*. *See, Frankum v. Boston Scientific Corp.*, Case No. 1:15-CV-091 (W.D.N.C.), January 4, 2016 Transcript of Pretrial Conference Hearing, attached hereto as **Exhibit 16,** at p. 29-30.

Because Dr. Blaivas clarified his 2014 deposition testimony, has unequivocally stated that he utilizes the same degree of academic rigor in his role as litigation expert that he does in his medical practice, and has since published a peer reviewed medical review article, the Court should not exclude his opinions.[4]

B. Dr. Blaivas' Opinions on the Complication Rates of Defendants' Products are Reliable, the Product of Sound Methodology and Will Assist the Finder of Fact[5]

Defendants allege that Dr. Blaivas' opinions regarding the safety of the TVT Devices should be excluded because: (1) his opinions are premised on an "unreliable assessment of complications and complication rates;" (2) he "selectively chooses" which literature to cite in support of his opinions; and, (3) he holds a "flawed assessment of pain, dyspareunia, sexual dysfunction, erosion, extrusion, exposure and infection data." *See*, Def. Brief at pp. 3-12. Each of these reasons is without merit and should be rejected by this Court.

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[4] Defendants also assert that Dr. Blaivas' opinions should be excluded to the extent he departs from statements made in a 2013 article authored by Dr. Blaivas in which the statements, "the etiology of mesh sling complications is a matter of conjecture" and that "surgeon error may be to blame" were made. This is a red herring because, (1) Dr. Blaivas stands by the statements in his article, *see*, Def. Ex. J at 397:16-19 ("I bring up theoretical reasons why – different reasons why complications can occur. I stand by that."); and (2) any question as to whether Dr. Blaivas continues to stand by statements he made in any particular article he authored goes to the weight to be accorded to that evidentiary material and not to its admissibility. *See Daubert*, 509 U.S. at 596; *see also Tyree*, 2014 WL 5320566 at *45.

[5] Plaintiffs object to Defendants' incorporation of sections from other memoranda submitted to exclude other experts as lacking in particularity as required by F.R.C.P. 7(b)(1). Defendants on page 7 of their Brief reference "Ethicon's brief supporting its motion to exclude Dr. Scott Guelcher's general opinions." Defendants have failed to specify in *this* Motion the basis for these objections, and they should therefore be denied. Further, Plaintiff should not have to guess what arguments are incorporated from their brief to exclude Dr. Guelcher.

1. Dr. Blaivas' Opinions on Complication Rates are Reliable.

Defendants' arguments are essentially an attack on the methodology employed by Dr. Blaivas in co-authoring a 2015 article published in the Nature Reviews Urology Journal entitled "Safety Considerations for Synthetic Sling Surgery." *See generally*, Ex. 2. The purpose of the article was to "summarize the published literature regarding complications that are *uniquely associated with SMUS* [*synthetic midurethral slings*] and to present an overview of complications that are not unique to these slings. *Id.* at p. 1 (*emphasis added*). To reach their conclusions the authors executed a "systematic review of the English language literature" in August 2014 to "investigate the published efficacy, effectiveness and complications of SMUS." *Id*. at p. 21. The search resulted in an initial 249 studies. After crosschecking their research, an additional eighty-eight (88) articles were included. The Safety Considerations article includes 397 total citations. Only articles published since 2007 were included in the complications review (to expand on an article published in 2008). *Id*. The Safety Considerations article represents arguably one of the most ambitious and comprehensive reviews for the safety of SMUS to date. The authors found the overall risk of a serious complication or surgical failure from the use of synthetic midurethral sling to be 12.5%. *Id*. This conclusion relates to all synthetic midurethral slings (not TVT alone). However, as this Court has previously held, "Dr. Blaivas' opinions as to polypropylene mesh slings generally are still helpful to a jury here." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 562 (S.D.W.Va 2014), as amended (Oct. 29, 2014).

As an initial matter, Defendants' attacks on the methods and basis for Dr. Blaivas' Safety Considerations article are not a legitimate reason to exclude the opinions set forth in Dr. Blaivas' Expert Reports, which encompass all of the opinions that Dr. Blaivas intends to give at trial. Rather, any attacks on one specific article written by Dr. Blaivas should be utilized as

ammunition for cross-examination. Nonetheless, Defendants assertions that Dr. Blaivas' opinions stemming from, in part, his Safety Considerations article are misplaced.

Defendants first argue that, because Dr. Blaivas could not give his same complication rate of 12.5% when he offered opinions in the *Huskey* case nearly two years ago[6], Dr. Blaivas should therefore be barred from giving this opinion now. *See*, Def. Brief at p. 4. On the contrary, it is the very analysis conducted by Dr. Blaivas *et al.* in 2015 in this peer-reviewed, published study that allows Dr. Blaivas to opine as to the complication rates of synthetic midurethral slings today. In fact, the exact reason that Dr. Blaivas was not allowed to opine on the complication rates of midurethral slings in the *Huskey* case was because he had not conducted this analysis. Now that he has and since his article has passed the rigorous peer-review process, Dr. Blaivas' opinions as to the 12.5% complication rate of SMUS should be admitted.

Not surprisingly, Defendants attempt to attack the reliability and integrity of Dr. Blaivas' Safety Considerations article, but their arguments are meritless and must fail. First, Defendants note that Dr. Blaivas and two of his four co-authors are Plaintiffs' experts in mesh litigations. Def. Brief at p. 4. This argument is null. As this Court has held, "[t]hat an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture." *See*, *Tyree*, 54 F. Supp. 3d 501, 518 (S.D.W.Va. 2014), as amended (Oct. 29, 2014) 562, *citing Daubert v. Merrell Dow Pharm. Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). Notably, each of the authors was involved in mesh research and publications *prior* to being retained as experts in this litigation and were retained by Plaintiffs because of the non-litigation expertise each had relating to mesh complications. *See*, *Hoffman v. Monsanto Co.*, No. 2:05-CV-00418, 2007 WL 2984692, at *3 (S.D.W.Va. Oct. 11, 2007) (considering additional factors to the *Daubert* analysis, "[w]hether experts are proposing to

[6] Plaintiffs' expert reports in the *Huskey* case were due on February 21, 2014. *See*, PTO 116.

testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." (*quoting* Fed.R.Evid. 702 advisory committee's note.)

Defendants' next argument is that the opinions set forth in Dr. Blaivas Safety Considerations article are unreliable because Dr. Blaivas allegedly was "unable to explain the calculation." Def. Brief at 5, *citing* Def. Ex. H at 227:22-229:24. However, a review of the deposition lines cited by Defendants reveals that Defense counsel never actually asked Dr. Blaivas how the 12.5% complication rate was calculated. Rather, Defense counsel asked Dr. Blaivas why one portion of the paper quoted a 12.5% complication rate and another portion of the paper quoted a 15% chance of negative outcome. Dr. Blaivas easily answered this inquiry:

> A. What I testified to before is somewhere between – the minimum number is somewhere between 12.5 and 15 percent.
>
> Q. And that number wasn't report in this paper, though; it was 12.5 percent.
>
> A. No, it's reported in – we calculated it a few different ways. And in the abstract, which is at the beginning of the paper, it gives a higher number.
>
> Q. Why did you decide to include, in the conclusion, that the overall risk was 12.5 percent?
>
> A. We calculated – I'd have to see the paper. But we calculated it slightly differently. And, I mean, quite honestly, the paper went back and forth for a number of different reviews. And I'm not confident that the – both numbers are correct, they're just calculated differently. They include different – they include different complications, and I'd have to go through – let me get the paper out. See, here I say, Furthermore, at least one-third of the patients undergoing excision – undergoing excision surgery developed recurrent stress incontinence. Considering the risk of refractory overactive bladder, fistulas and bowel perforations, among others, the overall risk of the negative outcome is about 15 percent. I didn't include all of those things in the calculations in the conclusions. I'm just looking – so, for example, in this conclusion, it doesn't include the other rare complications like bowel – like bowel injury and life-threatening sepsis and things like that. So there – they are both reasonably – they are both correct, but they – one includes more complications than the other.

Def. Ex. H at 227:22-229:24. This is nothing more than a subject for cross-examination should Defendants chose to go down this path at trial.

Defendants also argue that the 12.5% complication rate quoted by Dr. Blaivas in his Safety Considerations article should be stricken because it "assumes the worst-case scenario." Def. Brief at 5. However, Defendants are simply wrong. Dr. Blaivas testified that the 12.5% complication rate was *the minimum* complication rate and did not include many risks, including refractory overactive bladder, fistulas and bowel perforations and the article itself plainly states, "We calculated the overall risk of a serious complication or surgical failure to be 12.5%. We emphasize though, that these data represent the absolute minimum rate of complications reported in the literature; the actual rate might be considerably higher." Ex. 2 at p. 21. Defendants also argue that the 12.5% figure is still overinflated because it encompasses other synthetic midurethral slings besides the TVT devices. Def. Brief at p. 6. However, two paragraphs later, Defendants lump their TVT devices into the category of all synthetic midurethral slings because Defendants want to benefit from Dr. Blaivas' opinions regarding Type I mesh as optimal for use in midurethral slings. Def. Brief at p. 7. While Dr. Blaivas' most recent publication does indeed state that Type I (knitted monofilament and macroporous polypropylene) mesh is currently considered to be the optimal material for a synthetic midurethral sling, Dr. Blaivas has never testified that any synthetic mesh is the optimal material for surgical repair above the autologous sling. *See*, Ex. 2 at p. 11, *see also*, Def. Ex. H at 141:2-16 (Q. We just looked at your review paper that said that Amid Type I macroporous polypropylene mesh, and you cited PROLENE®, is the preferred material. A. I said that. And it was also my opinion that the risk/benefit ratio using that is unacceptable. So that needs to be improved.) (Objections omitted). Defendants flip flop on this issue, embracing the TVT being lumped in with all synthetic slings when it is to their

benefit (such as when discussing the efficacy of midurethral slings or Type I mesh). However, when the conclusions regarding synthetic slings are not to Defendants' liking, they insist that the TVT is separate and apart from all other synthetic midurethral slings. Defendants cannot have it both ways. Furthermore, as this Court held in *Tyree v. Boston Scientific Corp.*, Dr. Blaivas' opinions on "polypropylene mesh slings generally are still helpful to a jury here." 54 F. Supp. 3d 501, 562 (S.D.W.Va. 2014), as amended (Oct. 29, 2014) 562.

Defendants next argue that Dr. Blaivas' opinions on the complication rates of midurethral slings as quoted from his Safety Considerations article should be excluded because he did not include certain studies that Defendants allege should have been captured by Dr. Blaivas and his research team in a table regarding efficacy. Def. Brief at p. 5-6. Defendants allege that Dr. Blaivas admitted that certain studies should have been included in Table 1 in his Safety Considerations article but were not. Def. Brief at 6. Defendants misconstrue the testimony of Dr. Blaivas. Indeed, much time was spent during Dr. Blaivas' deposition reviewing articles that Defense counsel alleged fit the criteria for Table 1, but were not included in Table 1. *See generally*, Def. Ex. H at 325:17-340:7.

However, this argument is a red herring – factually and legally. Specifically, Table 1 of Dr. Blaivas' article concerned articles on the long-term efficacy of midurethral slings. Many of the articles raised by Defense counsel were not relevant to the efficacy matters – but *were* included in the footnotes of Dr. Blaivas' Safety Considerations article and were considered by Dr. Blaivas and his team in reaching their 12.5% complication rate. Def. Ex. H at 407:21-414:21. Furthermore, Dr. Blaivas and his colleagues only included the most recent published article from a cohort when reporting on efficacy considerations in Table 1; thus, not all of the studies that Defendants believed should have been included in Table 1 were for appropriate reasons. Def.

Ex. H at 412:16-413:24. Finally, Ethicon's lawyers asked Dr. Blaivas about an additional 10-12 hypothetical studies that were not included in Table 1 *without identifying such articles for Dr. Blaivas*. In the absence of such identification, Dr. Blaivas was not able to identify the articles to which Ethicon's lawyers referred; was not able to identify whether the hypothetical articles even existed was not able to determine if they should or should not have been included in Table 1. *Id.* at 414:1-21.

Even if Ethicon's factual account were correct, it still would not preclude Dr. Blaivas from offering opinions in these cases. As this Court has held, "failure to review particular documents goes to the weight of his opinion, not its admissibility." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D.W.Va. 2014); *see also, Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 538 (S.D.W.Va. 2014), as amended (Oct. 29, 2014), applying ruling in *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989, at *29. As such, these arguments should be ignored.

2. Dr. Blaivas did not "Selectively Choose" to Rely on Some Articles while Ignoring others.

Defendants' next argument is that Dr. Blaivas discounts literature that is contrary to his opinions without adequate explanation. Def. Brief at p. 7-8. However, Defendants' argument is without merit. When confronted with contradicting studies, Dr. Blaivas explained that he had considered and disagreed with those studies. For example, regarding the *Novara*[7] meta-analysis pointed out in Defendants' Brief (at p. 7-8), Dr. Bliavas stated:

> When I reviewed this article, what sticks out in my mind is **in this paragraph where it says evidence synthesis, the statements are contradictory**. I do not have any confidence that they – that they did the analysis correctly. **And, I'm sorry, I hope you**

[7] *See*, Novara G., et al. Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. European Urology 2010 Aug; 58(2):218-238, attached hereto as **Exhibit 17**.

> **don't want me to take the time now, but we can.** But basically, they say, well, this operation had more complications than this and less than this, and they make one statement; and then they make another statement that says something else comparing one operation to another one. **But when you look at them in their totality – what I actually did, I actually wrote them out. And I said, okay, this is greater than this and this is greater than that and this is greater than that. And it turned out that there were contradictions.** It was – the logic was incorrect. You can't – you can't have a better outcome in pubovaginal slings in one sentence and lesser outcomes in another, but it did."

Def. Ex. H at 276:14-277:21 (emphasis added).

Furthermore, Defendants' comments regarding the findings of the *Novara* article with regard to autologous slings are incorrect. The *Novara* meta-analysis included studies using cadaveric fascia, such as the *Basok* study, which is a completely separate product and procedure than the autologous sling product and procedure on which Dr. Blaivas opines. *See*, Ex. 17 at fn. 30. Therefore, the rates set forth in the *Novara* study, which includes the *Basok* study, are not comparable with Dr. Blaivas' opinions regarding autologous slings and is consistent with his skepticism towards the results of the *Novara* study. Defendants make essentially the same argument with regard to a study by *Abbott* et al, that Dr. Blaivas "selectively chose" literature. Def. Brief at 8. However, with regard to the *Abbot* article, Dr. Blaivas explained the reason why he did not rely on that article, he felt the follow-up time period was too short to reach their conclusions. Def. Ex. H at 314:16-315:9 ("I'm familiar with the methodology that came to those conclusions and the follow-up is simply too short to agree with their conclusion."). Furthermore, even with the short follow-up duration, the *Abbott* study found that in the sling only cohort, only 24.3% of patients *did not* undergo any time of intervention and 23.3% required more than two re-intervention surgeries.[8] As such, this article actually supports Dr. Blaivas' opinions and

[8] *See*, Abbott S, Unger CA, Evans JM, et al. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. Am J. Obstet. Gynecol. 2014; 210:163.e1-8, at 163.e7, attached hereto as **Exhibit 18**.

testimony. Further, as this Court has repeatedly held, and as as quoted previously in this Response, "failure to review particular documents goes to the weight of his opinion, not its admissibility." *Huskey*, 29 F. Supp. 3d 691, 735 (S.D.W.Va. 2014); *see also*, *Tyree*, 54 F. Supp. 3d 501, 538 (S.D.W.Va. 2014), as amended (Oct. 29, 2014), applying the ruling in *Sanchez*, 2014 WL 4851989, at *29.

3. Dr. Blaivas' Assessment of Data Regarding Pain, Dyspareunia, Sexual Dysfunction, Erosion, Exposure, Extrusion, and Infection are Reliable under Daubert.

Defendants next argue that Dr. Blaivas' assessments of Pain, Dyspareunia, Sexual Dysfunction, Erosion, Exposure, Extrusion, and Infection data are flawed. Def. Brief at 9-12. Defendants' arguments are based, in part, on the 2009 AUA guidelines that Dr. Blaivas helped write, and alleged discrepancies between the information set forth in the AUA guidelines as compared to Dr. Blaivas Safety Considerations article. Def. Brief at 9. The mere fact that the AUA guidelines contradict the findings in Dr. Blaivas' Safety Considerations article does not make the article unreliable or flawed in any way. Dr. Blaivas testified that he did not agree with the ultimate findings of the AUA guidelines. Furthermore, the AUA guidelines were published in 2009, prior to the drastic uptick in literature related to mesh-related pain, which demonstrated how under-reported and serious such complications were. Most of the articles cited in Dr. Blaivas' report on this point were published in 2009 or later. Further, Plaintiffs do not have to show that the assessment of their experts is unimpeachable or beyond debate or question. Rather, Plaintiffs must demonstrate that their experts' opinions are reliable. *See*, *Cisson et al. v. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W.Va., 2013). The Safety Considerations article provides ample citations to its statements regarding pain, dyspareunia and sexual dysfunction. *See*, Ex. 2 at 13-14, 17-18. Defendants further claim that Dr. Blaivas was unable to identify studies that demonstrate that synthetic sling patients have postoperative pain at six months or

later. On the contrary, Dr. Blaivas testified that, "it wouldn't take me long to find [the study], if you want to use your time for me to do that." Defense counsel ignored Dr. Blaivas' offer. Def. Ex. H at 260:23-261:1.

In its arguments regarding the erosion, exposure, and extrusion data, Defendants again try to group their TVT Products into the larger group of all synthetic slings so they can benefit from the findings of the SGS review, which found an exposure risk of 1.4%. The SGS review found an exposure rate for pubovaginal slings of 5.4%. Dr. Blaivas expressed disbelief as to that figure, but explained the rationale for his opinion:

> I've lectured – I mean, I've interacted with thousands, thousands of urologists and gynecologists worldwide. If 1 out of 20 patients had this complication, it's inconceivable to me that no one would have ever asked a question, how do you deal with an erosion. I can't walk down the street at the AUA or SUFU without someone asking my advice about how to deal with a mesh erosion. It's just – which happens, according to this table, 20 percent of the time it happens with a pubovaginal sling. The only thing I can think of – I don't even – I'll just see the papers and formulate an opinion.

Def. Ex. H at 298:11-299:4. Dr. Blaivas is an expert in his field, and physicians performing these procedures from around the world seek his opinions and advice, and yet no physician has ever asked or even mentioned exposures with regard to autologous slings – not in any lecture, classroom, or informal conversation. Regardless, the fact that this one review contradicts the 397 articles cited in Dr. Blaivas' Safety Considerations article does not render those articles or Dr. Blaivas' methodology unreliable.

Defendants next argue that Dr. Blaivas' opinions regarding contamination of Defendants' products after implantation should be excluded because, in Defendants' view, the literature cited by Dr. Blaivas in support of his opinions "refutes his opinion." Def. Brief at 11.[9] First,

[9] This argument underscores the disingenuous nature of Ethicon's attack on Dr. Blaivas. First, they criticize him for allegedly not considering articles; next they criticize him for considering articles yet disagreeing with them. The plaintiff notes that each of Ethicon's experts has also been presented with articles that contradict their opinions in these cases. If the standard is that

Defendants claim that the *Vollebregt* paper cited by Dr. Blaivas is unreliable because (1) it deals with mesh used in prolapse surgery, and (2) Defendants claim that the paper actually supports the safety of their products. *Id*. First, Dr. Blaivas is being offered to testify as an expert with regard to Defendants' Prolift POP product, so the article is relevant in that regard. Second, the *Vollebregt* paper discussed by Dr. Blaivas only addresses synthetic mesh implants. Thus, the authors' statement that Type I mesh has the "lowest risk of infection" is in relation to other meshes, not the risk of infection of autologous slings. Furthermore, the *Vollebregt* study found that despite sterilization measures, nearly all meshes were found to contain bacteria colonization from the vagina. Finally, none of Defendants' arguments should succeed because they are premised on an argument about the factual content of a scientific paper cited by Dr. Blaivas. Defendants' arguments are better suited for cross-examination on this topic than for exclusion of these opinions.

C. Dr. Blaivas' Opinions that Autologous Slings are a Safer Alternative to Synthetic Midurethral Slings are Relevant, Reliable and Have Been Admitted by this Court in Similar Cases.

Despite the fact that this Court has previously allowed Dr. Blaivas to testify as to the superior safety profile of autologous slings over synthetic slings, Defendants continue to argue that these opinions should be excluded. *See, Tyree*, 54 F. Supp. 3d 501, 560 (S.D.W.Va. 2014), as amended (Oct. 29, 2014); *Huskey* Tr. Day 5 at 184:4-191:13, Aug. 28, 2014, attached hereto as **Exhibit 19**; *see also*, Def. Brief at p. 12-17.[10]

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each opinion must stand uncontroverted from all sources, then Defendants' experts must also be excluded from testifying at trial.

[10] In its Brief, Defendants argue that based on the state law of individual Wave 1 plaintiffs, Dr. Blaivas cannot testify that autologous slings are a safe alternative to synthetic mesh because "autologous slings are not a device." *See*, Def. Brief at Footnote 7. A general Daubert Motion is not the proper forum to argue over state specific laws involving individual Wave 1 Plaintiffs; that argument should be in a case specific *Daubert* motion. Plaintiffs reserve the right to address

i. Dr. Blaivas' opinions regarding autologous slings as a reasonable and safer alternative to Defendants' MUS products are relevant to the jury and were reached using Dr. Blaivas' extensive experience coupled with a review of the medical and scientific literature

Defendants first argue that Dr. Blaivas' opinions regarding the safety of autologous slings should be excluded because they are based on "his own unreliable personal experiences." The fact that Dr. Blaivas does not use polypropylene slings in his own practice supports his opinions in this case and illustrates that his opinions are highly reliable and admissible – as they were clearly not formed for the purposes of litigation, but are opinions that he has researched and developed over years of clinical experience in his own practice. Plaintiffs do not have to show that the opinions of their experts are irrefutable; they only have to demonstrate that their opinions are reliable. *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W.Va. 2013).

Further, the methodology employed by Dr. Blaivas in forming his opinions in this case is proper:

> Q. What was the methodology that you used in developing the opinions that you hold in your expert report that was produced in this case as opposed to the "Nature" article?
>
> A. The methodology was – first, my own personal experience with mesh, with mesh complications and with my firsthand knowledge of what my peers and the medical communicate at large that I interact with, what their opinions were and what they knew about the potential use of mesh to cause complications and what they knew about the science behind the theories that led to the use of mesh and their knowledge of the complications that had occurred in the past and were occurring during the present, whenever that was.
>
> So the first part of my answer is my own personal experience with all of these things. The second part is my review of the medial literature and tempered with a third part is my rather unique awareness of the medical literature because I was editor and chief for so many years of the major journal that dealt with these kinds of things. And I was also either on the editorial board or a reviewer for the other medical journals that dealt with this. So I had a perspective of all of the quality of the studies that were submitted for peer review and the methodology and I think it gave me a unique perspective on understanding the differences between the methodology that they use for complications versus the methodology they use for safety – excuse me, for efficacy.

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these arguments with legal briefing on these issues at the appropriate time or supplement this Response as requested by the Court.

Def. Ex. H at 398:10-399:20. Dr. Blaivas' opinion that autologous pubovaginal slings are safer than synthetic mesh slings, and that the success rate for autologous slings is comparable to synthetic mesh slings is supported by his own personal experience and a review of the medical literature. *See*, Def. Ex. B at ¶20-24. Further, Defendants argue that Dr. Blaivas should not be allowed to give these opinions because he has never implanted a TVT. Def. Brief at 14. There is no requirement under *Daubert* that Dr. Blaivas must compare the outcome of patients he has implanted with autologous slings to the outcomes of patients he has implanted with a TVT device in order to form a reliable opinion – and Defendants provide no support for such a claim. In fact, using Defendants' logic, their own experts would be unable to testify about the efficacy of the TVT devices unless they had a significant group of their own patients in whom they had implanted autologous slings or other manufacturers' synthetic mesh products. Nor is there case law supporting Defendants' arguments that Dr. Blaivas' experience using autologous slings needs to be representative of other physicians' experiences implanting autologous slings to testify about it. In reality, it is Dr. Blaivas' exceptional experience coupled with his exhaustive review of the literature that qualifies him as an expert in this litigation.

Defendants also argue that Dr. Blaivas' opinions regarding autologous slings should be excluded because "there are no reliable medical studies" that support his opinions. Def. Brief at 15. This argument is irrelevant. Dr. Blaivas' spent much of his deposition explaining that the medical literature for *all slings*, synthetic and autologous alike is generally poor. For example, the AUA stress incontinence guidelines found that the overall quality of evidence available to evaluate the safety and efficacy of *all slings*, including synthetics, was very poor:

> Although more than a decade has passed since the recommendations for improving the quality of data from clinical trials and studies were proposed by Leach et al., very little progress has been made by editors and reviewers in instituting these recommendations. Furthermore, the FDA has not altered the approval process as discussed below. Thus,

> again, the Panel members were extremely disappointed in data available for meta-analysis.

AUA Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update, attached hereto as **Exhibit 20**[11]; *see also*, Def. Ex. H at 99:16-24. This "poor" pool of literature is the same one from which Defendants' experts have pulled support for their own opinions.

Defendants further and erroneously state that Dr. Blaivas is not familiar with the literature comparing autologous slings with synthetic slings such as the TVT Devices. In reality, Dr. Blaivas cited to many studies in support of his opinions regarding the safety and efficacy of autologous slings as outlined above. An example of Dr. Blaivas' in depth knowledge of the literature on this topic was shown when Defense counsel asked Dr. Blaivas about current studies regarding autologous slings. Dr. Blaivas was able to identify studies by Eric Rover and Roger Dmochowski's group off the top of his head. Def. Ex. H at 106:1-7. In fact, Dr. Blaivas summarized his opinions on autologous slings and the methodology utilized to form those opinions succinctly during his deposition:

> Q. Now, you also talked about the quality of literature on pubovaginal slings. Do you recall that?
> A. I do.
> Q. And I believe you said that the quality of the literature was "poor." Do you remember saying that?
> A. Yes.
> Q. Okay. Is there sufficient evidence in your opinion in the literature to base the opinions that you've offered here on the safety and efficacy of the pubovaginal sling?
> A. Okay. For the safety – excuse me. For the efficacy, yes, and – but my opinion for safety is based not only on the medical literature, which I've already said I think when it comes to safety is poor, but my review of what's not in the literature. So I suppose in a sense that's a review of the literature. So I'm going to say, yes, it is based on the medical literature.

[11] The AUA Guidelines publication is 280 pages long. For convenience and the sake of brevity, only the relevant portions have been included as an exhibit hereto. The entire publication is available at www.auanet.org/common/pdf/education/clinical-guidance/incontinence.pdf

> Q. Okay. Do you rely on anything else besides the published literature concerning your opinions on the safety and efficacy of the pubovaginal sling as set forth in your report?
> A. Very very much so. And, in particular, for the last 20 years I've been running – I've been either co-chairman or chairman or faculty member of courses that where in—in which we always have sessions on complications. And we have whole sessions on complications of mesh slings. There's always, you know, half a day or, at least, an hour or two on mesh sling complications. We don't have – this is even going back 25 years ago. We never had – we never had such discussions of complications for autologous slings.
>
> And, again, Burch's just weren't done that much in the environment that I was in. It would be restricted to autologous slings. There just wasn't concern about it. The complications from autologous slings where the sling was too tight or not and caused obstruction, which could be relatively easily fixed by cutting the sling, or it caused de novo overactive bladder symptoms. But there were never whole sections of seminars devoted to pelvic pain or pain after slings. It just didn't exist. So – and it doesn't exist in the literature other than in a few, in my judgment, poorly done studies. So all that led me to believe that complications after mesh slings are serious and serious problems that occur often enough to capture the attention of both academics and doctors in practice. Whereas complications from autologous slings were pretty much limited to those two complications that I said.

Def. Ex. H at 403:16-406:11. Dr. Blaivas' opinions on this topic should be allowed in full.

D. Dr. Blaivas' Design Opinions are Reliable and Dr. Blaivas is Qualified to Give Such Opinions

Dr. Blaivas' opinions regarding the use of lighter-weight, larger-pore mesh to reduce complications and improve patient outcomes are not only supported by the medical literature, but also by Defendants' own documents, testing, and admission. Dr. Blaivas is indeed qualified to offer these opinions at trial. He has published extensively on surgical repairs to treat urinary incontinence in women, the complications of mesh urinary incontinence repairs, and, as discussed above, his most recent publication details the literature to date related to the safety profile of synthetic midurethral slings, including the clinical consequences of using lighter-weight, larger pore meshes as opposed to heavier weight, smaller pore meshes. *See*, Def. Ex. B at 11, fn. 35, 294-300, 16, fn. 35, 343, 357, at 17, fn. 366. In his report, in addition to the aforementioned extensive literature review and accompanying article, Dr. Blaivas cited to numerous Ethicon documents (including Ethicon's own testing of it's TVT Devices) to support

his opinions. *See, Id*. at p. 16, fn. 89. In addition to his own article, Dr. Blaivas cites to an additional six (6) scientific articles which support his opinions regarding clinical outcomes with lighter-weight mesh. *Id*. at fn. 88. Dr. Blaivas further references Ethicon's own documents and testimony of Ethicon employees which demonstrates that Ethicon began using lighter-weight mesh in its hernia repair and pelvic organ prolapse products to avoid these complications. *Id*. at ¶ 52. Ethicon further argues that Dr. Blaivas should not be allowed to opine on the differences between machine-cut versus laser-cut mesh, to include opinions about the TVT-O and TVT-Abbrevo. See, Def. Brief at p. 21-23. Ethicon's own documents support Dr. Blaivas' opinions regarding these topics. Def. Ex. B at ¶ 44-50, *see also*, Def. Ex. T. In fact, Ethicon documented that particle loss for the mechanical-cut TVT rates were higher than the synthetic slings of other manufacturers. *Id*. Dr. Blaivas is qualified to render these opinions and they are well-supported by both the scientific literature and Defendants' own documents and testimony, and should therefore be admitted.

E. Dr. Blaivas has Designed a Sling Using Defendants' Flat Mesh Product and is Qualified to Testify on Design and His Opinions are Reliable.

Unlike the Boston Scientific mesh in *Tyree*, Dr. Blaivas has used Defendants' flat mesh product to design a sling for implantation in a very select group of patients. *See*, Def. Ex. H at 20:11-22:22. Dr. Blaivas also designed the method and chose the devices used to insert this mesh sling. *Id.* at 30:19-32:5; 38:16-40:15; 397:15-398:1. Additionally, Dr. Blaivas has placed approximately 1,500 autologous slings using Ethicon's Prolene suture. *Id*. at 43:2-6. This experience qualifies Dr. Blaivas to opine on the design characteristics of Defendants' products.

Contrary to Defendants' assertions, Dr. Blaivas explained at length how he would change Defendants' implantation procedures. *Id.* at 127:8-135-10. Furthermore, just because Dr. Blaivas' opinions contradict with a single study does not mean that Dr. Blaivas has "selectively

chosen" information to support his opinions. Def. Brief at 23. Nor does it mean that Dr. Blaivas' opinions must be excluded. *See*, *Tyree*, 54 F. Supp. 3d 501, 558 (S.D.W.Va. 2014), as amended (Oct. 29, 2014), "[g]eneral acceptance is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence…" *citing Daubert*, 509 U.S. at 597.

Defendants also inaccurately argue that Dr. Blaivas has not provided adequate support for his opinions that the trocars used in Defendants' products can cause organ perforations. Def. Brief at 23. Defendants completely ignore the numerous citations supporting Dr. Blaivas' opinions regarding complications, including Defendants' own document entitled "Most Significant Reported Complications" cited by Dr. Blaivas which lists injuries to patient bowels and vessels. Def. Ex. B at ¶ 5. Dr. Blaivas is qualified to offer opinions regarding Ethicon's mesh design and he uses his own extensive experience, peer reviewed published literature, and Defendants' own listing of product complications of the TVT procedure and should therefore be admitted.

F. Since this Court's Prior Rulings, Dr. Blaivas has Published a Peer-Reviewed Article Regarding Mesh Shrinkage and Degradation.

Since this Court's orders in *Tyree* and *Huskey*, Dr. Blaivas has published his article on the Safety Considerations of Midurethral slings which supports his opinions regarding mesh shrinkage and degradation, and Dr. Blaivas provides extensive citations to the scientific literature to support his opinions in that article. *See*, Ex. 2 at 11, fn. 35, 394-400, at 14, fn. 38, 330, at 18, fn. 103 (mesh shrinkage); at 3, fn. 26-28, at 7, 16, 17, fn. 36, 37, 341, 351-353, 355, 358-366, at 20, fn. 357-359, 361, 366, 386, 387. Dr. Blaivas' experience in treating women with these complications and his newly published, peer-reviewed research qualifies Dr. Blaivas to offer opinions regarding mesh shrinkage and degradation, and he has offered ample citations to

scientific literature to support those opinions. As a physician, Dr. Blaivas regularly examines mesh, both in vivo during pelvic exams of patients and upon explant following surgery. Def. Ex. H at 387:15-24. In addition to relying on his own experience for his opinions regarding the deformation of Defendants' devices, Dr. Blaivas' opinions also stem from Defendants' own documents, which illustrate complaints of deformation received by Ethicon. Def. Ex. B at ¶ 45-46.

G. Dr. Blaivas has Provided a Reliable Basis and Methodology for his Opinions that Defendants' Devices Present a Heightened Risk of Death and Other Complications.

Defendants seek to exclude Dr. Blaivas' opinions regarding Defendants' devices as causing death, cancer, chronic mesh pain syndrome, and mesh cripples. Def. Brief at 26-27. Dr. Blaivas' opinions on these life-altering complications are relevant, reliable, and Dr. Blaivas is qualified to offer such opinions. In fact, Dr. Blaivas finds these complications prevalent and important enough to warn his own patients about these risks in his own practice. Def. Ex. H at 23:21-25:8. In fact, Dr. Blaivas specifically included pain as a risk that is one of the many risks that are "common enough and/or lifestyle altering enough that would make you consider not having the operation." *Id*. at 23:21-25:8. Interestingly, although Defendants now refer to these conditions as "inflammatory" and "alleged," Defendants listed these conditions in their own internal document entitled "Most Significant Reported Complications" cited by Dr. Blaivas in his Reports. Def. Ex. B at ¶ 5. [12] Defendants also take issue with Dr. Blaivas' testimony regarding Chronic Mesh Pain Syndrome, but in support of his opinions on this topic, Dr. Blaivas cites to a chapter entitled "Pain Complications of Mesh Surgery" in the academic textbook *Complications of Female Incontinence and Pelvic Reconstructive Surgery*. *See*, Def. Ex. B at ¶ 4,

[12] ETH.MESH.0066048. This list includes 11 deaths reported with the TVT as of February 2, 2006. The document also lists complaints of injuries to bowel, urethra, and vessel, hematomas, infection and nerve injury.

fn. 6. The term "Chronic Mesh Pain Syndrome" is also recognized in the peer- reviewed scientific literature.[13]

Furthermore, unlike in *Huskey* where the key inquiry for the jury was whether a single plaintiff's injuries were caused by Defendants' product, the relevant inquiry here is whether six (6) of Defendants' devices and procedures are reasonably safe and can cause harm to women. Dr. Blaivas' opinions regarding the increasing number of women with disabling injuries is clearly relevant to the safety of Defendants' devices in women and will assist the jury in its findings.

H. Dr. Blaivas' Opinions on Defendants' Product Warnings are Relevant and This Court has Previously Admitted Dr. Blaivas Testimony on those Topics.

Despite the fact that this Court allowed Dr. Blaivas to testify as to product warnings in the *Huskey* trial, Defendants now argue that Dr. Blaivas' opinions regarding product warnings in this case should be excluded, citing to a single line of Dr. Blaivas' August 2015 deposition where he testified that he is not an expert on product warnings. Def. Brief at 27. However, as this Court held in *Huskey*, Dr. Blaivas need not be an expert on product warnings to give the opinions set forth in his Expert Reports, "[D]r. Blaivas need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warning and – 'it follows from that – the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits' of the TVT-O was when the warnings were published." 29 F. Supp. 3d 691, 719 (S.D.W. Va. 2014), *quoting*, *In re Diet Drugs (Phentermine*,

[13] *See*, Dallenbach, P. "To Mesh or Not to Mesh; A Review of Pelvic Organ Reconstructive Surgery," Int. J. of Women's Health, 2015: 7, 331-343, attached hereto as **Exhibit 21.**

Fenfluramine, Dexfenfluramine) Prods. Liab. Litig., MDL 1203, 2000 WL 876900 at *11 (E.D. Pa. June 20, 2000). The same logic applied by the Court in the *Huskey* trial should be applied here. Because Dr. Blaivas is qualified to testify about the risks of implanting Defendants' products through his experience as a urologist, he is qualified to testify regarding his opinions as to whether or not those risks were adequately expressed in Defendants' product warning labels.

I. Dr. Blaivas is Qualified to Offer Opinions Regarding the Testing of Defendants' Products and His Opinions are Relevant and Helpful.

This Court has *not* previously excluded Dr. Blaivas' opinion that Defendants' products should not have been designed for placement in a surgically contaminated field without proper animal and clinical testing studies to document safety and without a clear warning about the possibility of short and long term complications. This opinion goes to the quality of evidence available to Defendants prior to marketing their devices and procedures for implanting those devices. In his role as a physician, journal editor, researcher, professor and author, Dr. Blaivas regularly evaluates clinical studies and the quality of evidence and testing utilized in those studies to formulate scientific opinions. Furthermore, in his reports, Dr. Blaivas cites to published, peer-reviewed literature to support these opinions. *See*, Def. Ex. B at ¶ 3, fn. 4.

Additionally, Dr. Blaivas is uniquely qualified to comment on the safety considerations of the procedures utilized to implant Defendants' products. His recent article, Safety Considerations, summarized the peer-reviewed published literature regarding complications that are uniquely associated with synthetic midurethral slings and presented an overview of complications that are not unique to these slings. This Court has not previously excluded Dr. Blaivas' testing opinions, Dr. Blaivas is qualified to offer said opinions, and his opinions are based on a reliable methodology and review of peer-reviewed scientific literature.

J. Dr. Blaivas is Qualified to Render Opinions Related to Industry Bias and Manipulation in Medical Literature, and These Opinions are Reliable.

Dr. Blaivas, in his capacity as a physician, researcher, professor and author, is continuously responsible for evaluating the quality of information and potential bias contained therein. In fact, as mentioned previously, Dr. Blaivas served as Editor-in-Chief of the Neurourology and Urodynamics Journal for twenty-six years. This role alone qualifies Dr. Blaivas to tell the jury about the potential for industry bias in evaluating scientific literature. In his reports, Dr. Blaivas goes into great detail regarding the effects of industry bias on the scientific landscape and on specifically on Defendants' influence over investigators who studied and reported on the safety of Defendants' products. *See*, Def. Ex. B at ¶ 37-43. Further, this Court has previously allowed Dr. Blaivas to testify regarding bias in the *Ulmsten* and *Nilsson* studies, holding if Defendants, "[s]eek to challenge Dr. Blaivas' allegations of bias as to these studies, it may do so on cross-examination." *Tyree*, 54 F. Supp. 3d at 559 (*citing*, *Daubert*, 509 U.S. at 596, 113 S.Ct. 2786).

Dr. Blaivas' opinions are further supported by his citation to his most recent publication, Safety Considerations, which provides additional citations to support his opinions regarding industry bias. Ex. 2 at p. 5. Dr. Blaivas is qualified to offer opinions regarding industry bias and he has provided substantial support, including peer-reviewed published literature and Defendants' own documents, to support these opinions.

K. Dr. Blaivas Will Not Offer Opinions on Defendants' State of Mind, Narrative Summaries of Defendants' Documents, or Marketing Opinions

Defendants' final argument in support of their Motion to Exclude the Opinions of Dr. Blaivas suggests that this Court should exclude any of Dr. Blaivas' opinions that are merely a narrative summary of Ethicon documents; are related to Ethicon's knowledge, state of mind,

alleged bad acts, failures to act, and corporate conduct and ethics; and marketing opinions. Def. Brief at 30. Plaintiffs do not intend to offer Dr. Blaivas at trial to give opinions on these topics.

CONCLUSION

For all of the above reasons, Dr. Blaivas is fully qualified to render the opinions he is called on to make and those opinions are based on a reliable methodology and will assist the jury. Consequently, his opinions are admissible and Defendants' Motion should be denied in its entirety.

Dated May 09, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on May 09, 2016, a true and correct copy of this Response, and exhibits, was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.